

Remarks

Rejection of the claims under 35 USC §103:

Claims 1, 3-7, and 10-20 have been rejected under 35 U.S.C. 103(a) as being anticipated by Wolff et al. (WO200075164) ('164) in view of Mathiowitz et al. (US 6,248,720) and Haines et al. (US 6,479,464). Applicants respectfully disagree. As Applicants argued in their letter of April 22, 2009, WO200075164 teaches away from covalent attachment of a nucleic acid to a polyamine (at page 3 lines 23-24, page 7 lines 18-19, page 19 lines 31-34, page 33 lines 8-12, and page 33 line 33 to page 34 line 2; these references were incorrectly identified in the previous office action as: 4 lines 1-2, page 7 lines 30-31, page 20 lines 9-11, page 33 lines 20-24, and page 34 lines 11-13).

The Action points to page 7 of '164 which teaches the use of DNA-polycation complexes and polycations are a convenient linker for attaching specific ligands to DNA. The Action argues that this section teaches attachment of DNA to the polymer. However, '164 teaches at page 33 lines 8-12 that a complex is formed *if* two molecules are in contact with one another through *noncovalent* interactions such as electrostatic interactions, hydrogen bonding interactions, and hydrophobic interactions. Therefore, '164 does not teach or suggest covalent attachment of the DNA to the polycation and specifically teaches away from covalent attachment in the formation of a complex.

The Action points to page 23 of '164 which teaches delivery of nucleic acids to cells by a polymer complex containing labile bonds. However, again, '164 teaches a *complex* containing labile bonds, and as noted above, '164 teaches that a complex is formed only from *noncovalent* interaction. Therefore, page 23 lines 21-24 of '164 teaches only that a polymer or a nucleic acid in a noncovalent nucleic acid/polymer complex can have a labile bond. As a whole, '164 teaches away from covalent attachment of the nucleic acid to the polymer. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)".

The Action points to page 25-26 of '164 which teaches that a biologically active compound, such as nucleic acid can be attached, through a labile bond, to a compound C which can

modify delivery or transport of the nucleic acid. However, '164 does not teach or suggest attachment of a nucleic acid via a labile bond to a membrane active polymer wherein the membrane active polymer is additionally reversibly modified. Applicants have further amended the claims to recite modification of a plurality of amines to carboxyl groups to form a polyanion. Support for modification of a plurality of amines can be found in the specification as originally filed on page 2 line 31 to page 3 line 7, page 3 lines 19-21, and page 5 lines 5-7. Support for attachment of carboxyl groups can be found in the specification as originally filed on page 4 lines 11-16 and FIG. 1. Support for forming a negatively charged polymer can be found in the specification as originally filed on page 2 lines 31-34 and page 5 lines 5-7. '164 does not teach or suggest covalent attachment of a nucleic acid to a polyanion. The courts found, In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995), in cases involving new chemical compounds, that it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound. More recently, in Takeda v. Alphapharm, 492 F.3d 1350 (Fed.Cir. 2007) the courts found that there is no *prima facie* obviousness found when the prior art teaches many compounds, only one of which, when modified, may lead to patentee's compound.

In view of the argument and amendments, Applicants request reconsideration or the 103 rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 3-4, 6-7, 10-13, and 15-20 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the USPTO on this date: 10/14/2009.

/Kirk Ekena/  
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